

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TRIANTAFYLLOS TAFAS,)
)
)
Plaintiff,)
)
v.)
)
)
JON W. DUDAS, et al.,)
)
)
Defendants.)
)

Case No. 1:07cv846 (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM)
CORPORATION, et al.,)
)
)
Plaintiff,)
)
v.)
)
)
JON W. DUDAS, et al.,)
)
)
Defendants.)
)

Case No. 1:07cv1008 (JCC/TRJ)

**DECLARATION OF BARBARA S. SCHILBERG IN SUPPORT OF *AMICUS CURIAE*
THE PENNSYLVANIA GREENHOUSES' BRIEF IN SUPPORT OF
PLAINTIFFS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT**

I, Barbara S. Schilberg, do hereby state the following:

1. I am Managing Director and Chief Executive Officer of BioAdvance, The Biotechnology Greenhouse of Southeastern Pennsylvania ("BioAdvance").

2. BioAdvance is principally a state-funded enterprise. BioAdvance, one of three Pennsylvania Greenhouses, was initially funded by monies received from the Commonwealth of Pennsylvania's share of The Tobacco Settlement Act of 2001. BioAdvance has received additional monies from the Commonwealth of Pennsylvania, as well as from returns on its investments.

3. BioAdvance's mission is to accelerate the growth of the life sciences industry in Southeastern Pennsylvania by transforming the region's strengths in biomedical research into commercial opportunities. BioAdvance was established in 2002 when awarded \$33.8 million from the Pennsylvania's share of tobacco settlement monies to grow the life sciences industry in Southeastern Pennsylvania.

4. BioAdvance invests up to \$1 million per company in emerging life sciences technologies with promising commercialization prospects, accelerates the transfer of technology from research laboratories to start-ups and established companies, assists in attracting, retaining, and supporting life sciences entrepreneurs, and builds collaborations between academic, entrepreneurial, corporate, financial, and government partners.

5. BioAdvance invests in companies developing, for example, therapeutic agents, diagnostics and devices to improve human health. Targeting entrepreneurs in the life sciences sector, BioAdvance has invested in companies working to develop products to treat many serious health problems including Alzheimer's disease, cancer, obesity, gastrointestinal disorders, neurological, and respiratory illnesses.

6. Since 2003, \$11.5 million has been invested in 21 companies and nine pre-seed projects by BioAdvance. In turn, these investment partners of Bioadvance have raised

almost \$200 million in additional capital since that time. Representative investments include Avid Radiopharmaceuticals, Inc., which is developing novel radiopharmaceuticals for early diagnosis of Alzheimer's disease; Protez Pharmaceuticals, Inc., which seeks to discover novel antibiotics to combat drug resistance in difficult-to-treat hospital-based infections; and Gelifex, Inc., which has developed novel spine implants for degenerative disc disease. Additional information about BioAdvance's investments may be found in Appendix A, attached hereto.

7. Patent protection is vital to the companies in which BioAdvance invests. Each stage of funding by BioAdvance in an early-stage life science companies depends, in large part, on the company's ability to obtain patents on the technologies and products that it has developed.

8. In my experience, the ability to obtain clear and comprehensive patent protection is a key element in attracting necessary additional capital investment, as well as corporate partners necessary to commence the costly research and development of life science inventions. Sustaining an adequate, ever-increasing level of financing and partnering during continued research and development, clinical investigations, regulatory approval, and commercialization of a life science product depends upon a funded company's ability to obtain comprehensive patent protection. The ability of an early-stage life science company to obtain capital is therefore directly tied to its intellectual property assets and particularly to its patent portfolio.

9. I am familiar with the final rules published by the United States Patent and Trademark Office ("PTO") on August 21, 2007 as Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and

Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (hereinafter “Final Rules”) (to be codified at 37 C.F.R. pt. 1).

10. BioAdvance opposes implementation of the Final Rules because, among other things, the Final Rules will shift the burden of examination onto patent applicants by requiring the preparation of an “Examination Support Document,” which will lead to an increase in legal fees, as well as unfairly restricted opportunities for obtaining patent protection.

11. In my experience, life science product development is extremely expensive. Early stage life science companies will be adversely affected if they are forced to allocate additional funds toward patent prosecution as a result of the proposed changes to the PTO’s rules.

12. If a life science company were to lose its basic patent coverage or be forced to give up the protections afforded by current continuation application practice, it is possible that BioAdvance and other investors may decline the next stage or round of investment because of the loss of patent exclusivity and the resulting economic disincentive to develop and commercialize new products.

13. In my experience, early-stage life science companies rely heavily on the certainty of the patent system to attempt to secure market exclusivity on any inventions so as to enable those companies and their investors to recover their investments. BioAdvance and its funded companies rely heavily on patent protection, as well as the current, established PTO rules of practice, to obtain adequate coverage for inventions and to attract the necessary financial investment to research, develop, and commercialize life science products.

14. I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct.

12/17/07

Date

Barbara Schilberg

Barbara S. Schilberg
Managing Director and
Chief Executive Officer
BioAdvance, The Biotechnology
Greenhouse of Southeastern Pennsylvania

APPENDIX A